IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

GENBIOPRO, INC.,

***Plaintiff*,**

v.

MARK A. SORSAIA*, in his official capacity as Prosecuting Attorney of Putnam County* AND PATRICK MORRISEY*, in his official capacity as Attorney General of West Virginia,*

***Defendants*.**

Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)

BRIEF OF FOOD AND DRUG LAW AND HEALTH LAW SCHOLARS AS AMICI CURIAE IN SUPPORT OF PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS

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INTRODUCTION AND SUMMARY OF ARGUMENT

Amici curiae are eight legal scholars from seven academic institutions across the United States, with expertise spanning U.S. food and drug law, health law, bioethics, and constitutional law.[1] Coming from a wide array of backgrounds, amici have published extensively and been quoted widely on topics related to the U.S. Food and Drug Administration (FDA or the Agency) and its regulation of medication abortion. Amici submit this brief to provide the Court with additional context on FDA's broad authority to regulate medication abortion, including the conditions under which patient access is permitted.

Since initially approving mifepristone in 2000, FDA has used its federally-based authority to govern how patients access the drug.[2] FDA first did so under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 355) and FDA's regulations in 21 C.F.R. Part 314, Subpart H, which were promulgated pursuant to the Agency's statutory authority under section 505 of the FDCA, and subsequently under section 505-1 of the FDCA (21 U.S.C. § 355-1), which authorizes FDA to implement drug safety programs known as risk evaluation and mitigation strategies (REMS) for certain drugs. From its original approval more than twenty years ago to the present, the prescription, distribution, and dispensing of mifepristone have been subject to a comprehensive and detailed federal statutory and regulatory scheme that imposes special restrictions beyond what is required for the vast majority of prescription drugs. Congress gave FDA the authority to balance risk mitigation, patient access,

[1] The views expressed herein are those of the amici in their individual capacities and do not necessarily represent the views of their respective institutions. A full list of amici is included as an Appendix to this brief.

[2] This brief uses "mifepristone" to refer to both the branded and generic forms of this drug that are approved for the medical termination of intrauterine pregnancy.

and burden on the health care delivery system, and at no point has Congress stepped in to override the balance that FDA has struck for mifepristone.

ARGUMENT

I. FDA Has Broad Authority to Regulate New Drugs for Use in the United States.

When Congress enacted the FDCA in 1938, it granted FDA the authority to oversee and regulate the introduction of food, drugs, medical devices, and cosmetics into interstate commerce. The FDCA established a comprehensive framework for FDA's pre-market review and approval of new drugs, requiring manufacturers to demonstrate that the drug was safe for its intended use and labeled with adequate directions for safe use. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 505, 52 Stat. 1040, 1052 (1938) (creating 21 U.S.C. § 355(a), (b)). In 1962, Congress enacted the Kefauver-Harris Amendments to the FDCA, strengthening FDA's pre-market approval authority over new drugs. For the first time, the statute expressly required manufacturers to show that new drugs were both safe and effective for their intended use in order to obtain FDA approval. Pub. L. No. 87-781, §§ 102, 104, 76 Stat. 780, 781, 784 (1962) (amending 21 U.S.C. § 355(a), (b)).

These broad FDA pre-market approval authorities remain today. Prior to marketing a new drug, a sponsor must file a New Drug Application (NDA) pursuant to section 505(b) of the FDCA, *see* 21 U.S.C. § 355(b), and demonstrate that the drug is safe and effective for the proposed indication, *see id.* § 355(d). The process for bringing a drug to market, however, begins long before submitting an NDA. In general, the manufacturer must first conduct studies of the drug in animals and then submit an investigational new drug application (IND) to the Agency to initiate human studies to support the NDA. On average, it takes 10 to 15 years to develop a new drug, submit an IND and NDA, gain FDA approval, and bring the drug to market. *See* Peter Barton Hutt et al., *Food and Drug Law: Cases and Materials* 629 (4th ed. 2013). Of

every 5,000 chemicals that enter preclinical testing, only five proceed to clinical testing and only one ultimately gains FDA approval. *Id.* Once an NDA is filed, FDA's rigorous review and approval process encompasses not only a clinical assessment of the drug itself but also, among other things, the "labeling proposed to be used for such drug." 21 U.S.C. § 355(b)(1)(A)(vi). FDA must refuse to approve an NDA if the Agency determines that there is "insufficient information to determine whether such drug is safe for use" under the proposed conditions of use, or a "lack of substantial evidence that the drug will have the effect it purports or is represented to have" under the proposed conditions of use. *Id.* § 355(d)(4), (5); *see also* 21 C.F.R. § 314.125(b).

Pursuant to its authority to ensure that new drugs introduced into interstate commerce are safe and effective, in 1992, FDA promulgated regulations governing the approval, use, and distribution of certain drugs "studied for their safety and effectiveness in treating serious or life-threatening illnesses" that "provide meaningful therapeutic benefit to patients over existing treatments." 57 Fed. Reg. 58942, 58958 (Dec. 11, 1992) (creating 21 C.F.R. Part 314, Subpart H). Subpart H established specific regulatory mechanisms to facilitate approval of such drugs under section 505(b) of the FDCA (21 U.S.C. § 355), including the imposition of conditions "needed to assure safe use" for certain drugs. 21 C.F.R. § 314.520(a). Between 1992 and 2007, FDA approved a limited number of drugs under this restricted distribution provision of Subpart H—one of which was mifepristone. U.S. Gov't Accountability Off., GAO-08-751, Approval and Oversight of the Drug Mifeprex 10 (Aug. 2008) (hereinafter 2008 GAO Report), https://www.gao.gov/assets/gao-08-751.pdf.[3]

[3] A separate provision of Subpart H (21 C.F.R. § 314.510), which is still in use, provides for accelerated approval based on a surrogate endpoint or on an effect on a clinical endpoint other (continued…)

In 2007, building on Subpart H's restricted distribution provision and FDA's voluntary risk management action plans (RiskMAPs),[4] Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), which gave FDA express statutory authority to impose use and distribution restrictions to address safety risks associated with pharmaceutical products, i.e., REMS. *See* Pub. L. No. 110-85, § 901(b), 121 Stat. 823, 926-49 (2007) (codified at 21 U.S.C. § 355-1). FDA can impose a REMS if it determines that a REMS is "necessary to ensure that the benefits of the drug outweigh the risks of the drug," taking into account, among other things, (1) "[t]he seriousness of the disease or condition that is to be treated with the drug," (2) "[t]he expected benefit of the drug with respect to such disease or condition," and (3) "[t]he seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug." 21 U.S.C. § 355-1(a)(1). While all prescription drugs are required to have labeling that informs health care professionals about drug risks, FDA has required a REMS for only a few prescription drugs. *See* U.S. Food & Drug Admin., *Risk Evaluation and Mitigation Strategies | REMS*, https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems (last updated Dec. 17, 2021).

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than survival or irreversible morbidity. FDA did not use that provision in connection with the approval of mifepristone.

[4] In 2005, FDA provided detailed guidance to drug product manufacturers about risk management activities throughout a drug product's lifecycle, including the voluntary development of RiskMAPs. These strategic safety programs used distribution restrictions, among other tools, to minimize a drug's risks while preserving its benefits. For example, a RiskMAP could require the use of a performance-linked access system that allowed a drug to be made available only if certain conditions were satisfied, such as a certification requirement for prescribers or pharmacies or a requirement that patients provide evidence of safe use (e.g., via lab test results). U.S. Food & Drug Admin., Guidance for Industry, Development and Use of Risk Minimization Action Plans 10 (Mar. 2005), https://www.fda.gov/media/71268/download.

Possible components of a REMS include, among other things, elements to assure safe use (ETASU). *See* 21 U.S.C. § 355-1(f). Much like the restrictions on use and distribution contemplated under Subpart H, ETASU are used if the drug has been shown effective, but FDA determines that the drug is associated with a specific serious risk, and it "can be approved only if . . . such elements are required as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug." *Id.* § 355-1(f)(1)(A). In determining whether to require ETASU for a drug and, if so, what the ETASU should entail, Congress directed FDA to conduct a balancing exercise, weighing the drug's specific risks against the burdens on patient access to the drug and on the health care delivery system. *Id.* § 355-1(f)(2).

As part of its 2007 amendments to the FDCA, Congress determined that drugs previously approved with elements to assure safe use under Subpart H were "deemed to have in effect" an approved REMS and required sponsors of such drugs to submit proposed REMS for approval by September 21, 2008. Pub. L. No. 110-85, § 909(b), 121 Stat. 823, 950-51 (2007), *reprinted at* 21 U.S.C. § 331 note. When FDA reviewed its records to identify medications approved before the effective date of FDAAA that were deemed to have REMS in effect under section 909 of FDAAA, it identified 16 drugs—including mifepristone. *See* 73 Fed. Reg. 16313, 16314 (Mar. 27, 2008).

II. Mifepristone Has Been Subject to More Regulatory and Congressional Scrutiny Than Perhaps Any Other Prescription Drug.

For more than twenty years, FDA has leveraged its broad statutory authority to tightly restrict mifepristone's prescribing, distribution, and dispensing, and it has done so under intense and consistent scrutiny from Congress. In May 1994, a nonprofit organization secured the rights for medical uses of mifepristone in the United States, and a U.S. clinical trial involving 2,121 women was initiated in October of that year. Judith A. Johnson, Cong. Rsch. Serv., Abortion:

Termination of Early Pregnancy with RU-486 (Mifepristone) 4-5 (Feb. 23, 2001), https://www.everycrsreport.com/files/20010223_RL30866_c6c423f682c56ed7c586755595c02d5202ddf6bd.pdf.[5] An NDA was submitted in March 1996. *See* U.S. Food & Drug Admin. Approvable Letter for NDA 020687 at 1 (Sept. 18, 1996), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_approvableltr.pdf. Almost immediately, certain members of Congress tried to exclude mifepristone from FDA's drug approval authority on the grounds that the FDA should not have the ability to research and approve medication abortion drugs. *See* Peter Grossi & Daphne O'Connor, *FDA Preemption of Conflicting State Drug Regulation and the Looming Battle Over Abortion Medications*, 10 J. L. & Biosciences 1, 21 (2023) (hereinafter *FDA Preemption of Conflicting State Drug Regulation*). Between 1998 and 2000, a Senator offered three amendments to the annual appropriation bill providing that "[n]one of the funds made available in this Act may be used by the Food and Drug Administration for the testing, development, or approval (including approval of production, manufacturing, or distribution) of any drug for the chemical inducement of abortion." *Id.* (citing 144 Cong. Rec. H5089-5100 (daily ed. June 24, 1998); 145 Cong. Rec. H3798-3812 (daily ed. June 8, 1999); 146 Cong. Rec. H5693-5709 (daily ed. July 10, 2000)). All of these amendments failed, as did three subsequent appropriation-constraining amendments targeting mifepristone. *See* Eli Y. Adashi et al., *The Next Two Decades of Mifepristone at FDA: History as Destiny*, 109 Contraception 1, 1-4 (2022) (listing failed amendments).

[5] The first clinical trial for mifepristone (then known as RU-486) began in Geneva in 1981, and the French government approved the drug as an abortifacient in 1988, following multiple successful clinical trials in France. *See* Greer Donley, *Medication Abortion Exceptionalism*, 107 Cornell L. Rev. 627, 636 (2022) (hereinafter *Medication Abortion Exceptionalism*).

In 2000, after thoroughly evaluating the clinical trials conducted in the U.S. and abroad and submitted over the span of several years, FDA approved an NDA for Mifeprex—the brand name for mifepristone, now distributed and marketed by Danco Laboratories, LLC ("Danco")—for the medical termination of intrauterine pregnancy through 49 days' gestation in combination with another drug, misoprostol. *See* U.S. Food & Drug Admin., Approval Letter for NDA 20687 at 1 (Sept. 28, 2000) (hereinafter 2000 Approval Letter), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf; *see also* 2008 GAO Report at 5. The mifepristone approval process took more than 54 months. 2008 GAO Report at 27. By comparison, on average, it took FDA approximately 18 months to approve NDAs for drugs submitted from 1996 through 2002. *Id.*

In approving mifepristone, FDA invoked Subpart H to impose restrictions on the drug's use and distribution, 2000 Approval Letter at 2, something the Agency has only ever done for a few drugs. Under the original FDA-approved label, the drug was to be administered in a clinic, medical office, or hospital (i.e., a health care facility) by or under the supervision of a physician meeting certain qualifications. *See* Mifeprex (Mifepristone) Tablets Label 14 (Sept. 28, 2000), https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.pdf. This not only meant that patients could not take the pill at home, but also that the types of providers who could administer mifepristone were substantially restricted. Among other things, a qualified physician needed to be able to "assess the gestational age of an embryo," "diagnose ectopic pregnancies," "provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others," and "assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary." *Id.* Additionally, the patient needed to complete three separate office visits—to take mifepristone on Day 1, to take

misoprostol on Day 3, and to attend a follow-up visit on Day 14. *Id.* at 14-15. As scholars have noted, these restrictions went beyond what FDA requires for most non-controlled substances. *See* David S. Cohen et al., *Abortion Pills*, 76 Stan. L. Rev. __ (forthcoming 2024) (draft at 13), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4335735 (discussing FDA's use of the restricted distribution provision in Subpart H as the Agency "regulat[ing] mifepristone *more* harshly than the vast majority of drugs, not more leniently or more expediently"); *Medication Abortion Exceptionalism* at 639; Patricia J. Zettler et al., *Mifepristone, Preemption, and Public Health Federalism*, 9 J. L. & Biosciences 1, 7 (2022).[6]

When Congress expressly authorized FDA to require REMS by enacting FDAAA in 2007, Pub. L. No. 110-85, § 901(b), 121 Stat. 823, 926-49 (2007) (codified at 21 U.S.C. § 355-1), it declared that drugs previously approved with elements to assure safe use under Subpart H were "deemed to have in effect" an approved REMS, Pub. L. No. 110-85, § 909(b)(1)(A), *reprinted at* 21 U.S.C. § 331 note. As noted above, this language applied to only 16 drugs. Congress was well aware that the "deemed to have in effect" language would sweep mifepristone into this new statutory scheme. Indeed, on the Senate floor, two Senators discussed the fact that, pursuant to the text of FDAAA, mifepristone would be distributed under a deemed REMS. *See* 153 Cong. Rec. S5759, 5765 (daily ed. May 9, 2007); 153 Cong. Rec. S5444, 5469 (daily ed. May 2, 2007).[7]

[6] At a May 2006 congressional hearing, there was debate about whether mifepristone's approval was proper and whether the Subpart H restrictions on use and distribution were sufficient to assure safe use, but no one claimed that FDA did not have the authority to approve or regulate mifepristone under section 505 of the FDCA or Subpart H. *See FDA Preemption of Conflicting State Drug Regulation* at 22 (citing RU-486: Demonstrating a Low Standard for Women's Health?, Hearing Before the Subcomm. on Crim. Just., Drug Pol'y, & Hum. Res. of the H. Comm. on Gov't Reform, 109th Cong., 2nd Sess. (May 17, 2006)).

[7] During the Senate mark-up, one Senator endorsed an amendment that would have suspended FDA's approval of mifepristone, but it was rejected. *GOP Fails to Narrow Scope of FDA* (continued…)

Pursuant to FDAAA and FDA's procedures to implement its REMS authority, Danco submitted a supplemental NDA (sNDA) with a proposed REMS for mifepristone in 2008, and FDA approved the mifepristone REMS, as amended, with ETASU in 2011. *See* U.S. Food & Drug Admin., Supplement Approval Letter for NDA 020687 at 1 (June 8, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/020687s014ltr.pdf.[8] The ETASU largely tracked the restrictions originally imposed under Subpart H. Though the 2011 REMS omitted some of the adverse event reporting requirements included in the original label, FDA retained, among others, the requirement that mifepristone be administered in a health care facility by a specially certified physician and the requirement that the patient complete three office visits. *See* U.S. Food & Drug Admin., Risk Evaluation and Mitigation Strategy (REMS) for NDA 20687 at 1-2, 5 (June 8, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2011-06-08_Full.pdf.[9]

Since 2011, the Agency has reevaluated and revised mifepristone's labeling and REMS on multiple occasions. In 2016, FDA approved an sNDA that, among other things, extended the gestational age for which the medication was approved for use from 49 days to 70 days; modified the dosing regimen for mifepristone and misoprostol; allowed a broader set of

Reform Bill During Senate Mark-Up, Inside Washington's FDA Week (Apr. 20, 2007). The engrossed Senate bill required the mifepristone manufacturer to submit a proposed REMS to FDA for approval on a more accelerated schedule than that applicable to manufacturers of other drugs. S. 1082, 110th Cong., 1st Sess., tit. II, § 214(b)(3)(B) (engrossed in Senate, May 9, 2007). However, the bill as enacted treated all drugs "deemed to have in effect" an approved REMS alike, requiring manufacturers to submit proposed REMS for approval by September 21, 2008. Pub. L. No. 110-85, § 909(b).

[8] Danco submitted the first draft of a proposed REMS on September 16, 2008, and subsequently submitted amendments on December 9, 2008, November 8, 2010, and May 19 and 27, 2011. FDA approved the REMS on June 8, 2011.

[9] In this brief, amici are not expressing any opinion on the scientific appropriateness of any version of the mifepristone REMS.

providers (beyond physicians) to become certified; allowed mifepristone to be dispensed in a health care facility and administered at home; and removed the requirement for additional office visits. *See* Mifeprex (Mifepristone) Tablets Label 2-4 (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020Lbl.pdf; U.S. Food & Drug Admin., Risk Evaluation and Mitigation Strategy (REMS) for NDA 20687 at 2-4 (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RemsR.pdf. Consistent with Agency practice, FDA used an internal team of experts (as it had for the original approval in 2000) to conduct medical, chemistry, pharmacology, statistical, clinical pharmacology, and biopharmaceutics reviews of all of the data submitted, including both the data submitted as part of the original application package and new data submitted as part of the sNDA application. *See* Mifeprex (Mifepristone) Tablets Review (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020TOC.cfm. The result was a determination by FDA that the drug was safe and effective with the revised indication, labeling, and REMS.

In 2019, FDA approved GenBioPro, Inc.'s generic version of mifepristone, *see* U.S. Food & Drug Admin., Approval Letter for ANDA 091178 at 1 (Apr. 11, 2019), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/091178Orig1s000ltr.pdf, and established a single, shared system REMS for both branded and generic mifepristone, U.S. Food & Drug Admin., Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 MG (Apr. 2019), https://www.fda.gov/media/164650/download.

Most recently, FDA has re-evaluated the in-person dispensing requirement of the mifepristone REMS. This restriction prevented a traditional telemedicine model under which patients could meet with a provider remotely from home and receive mifepristone by mail,

thereby burdening both patients and the health care delivery system. In April 2021, FDA announced that it would not enforce the in-person dispensing requirement during the COVID-19 public health emergency, if the other requirements of the REMS were met. *See* Letter from Janet Woodcock, Acting Comm'r of Food & Drugs, to Maureen G. Phipps, Chief Exec. Officer, Am. Coll. Obstetricians & Gynecologists, and William Grobman, President, Soc'y for Maternal-Fetal Med. 2 (Apr. 12, 2021). In January 2023, FDA completed another comprehensive review of mifepristone's safety and effectiveness and concluded that the "REMS must be modified to reduce burden on the health care delivery system and to ensure the benefits of the product outweigh the risks." U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (last updated Jan. 4, 2023). Under the current REMS, mifepristone can now be dispensed through specially certified retail pharmacies. *See* U.S. Food & Drug Admin., Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 MG 1 (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Full.pdf. Certification requires, among other things, that a pharmacy agree to certain record keeping, reporting, and medication tracking efforts and designate a compliance representative to implement these measures. *Id.* at 3-4, 11-12.

Notably, in exercising its authority to balance patient safety and access to mifepristone, FDA has expressly considered and rejected requests to re-impose restrictions from prior versions of the mifepristone REMS. In 2021, FDA denied a 2019 citizen petition that, among other things, sought to limit mifepristone's indication to 49 days' gestation, prohibit non-physician

health care providers from prescribing mifepristone, and require patients to make three different office visits to their physicians (i.e., to reverse the changes to the REMS made in the 2016 sNDA approval). *See* Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Amin., to Donna Harrison, Executive Dir., Am. Ass'n of Pro Life Obstetricians & Gynecologists, & Quentin L. Van Meter, Pres., Am. Coll. of Pediatricians 7-19 (Dec. 16, 2021). FDA also expressly considered and rejected claims that mifepristone could not be dispensed safely through telemedicine, determining that data submitted through the REMS program and the published literature demonstrate that the in-person dispensing requirement is no longer necessary to ensure that the benefits of the drug outweigh the risk. *Id*. at 22, 25-36.

CONCLUSION

Congress has assigned FDA the task of conducting pre-market review and approval of new drugs for use in interstate commerce and ensuring that all prescription drugs submitted to it for approval are safe and effective for their intended use. For certain drugs, Congress has vested FDA with additional authority to further oversee the drug's use and distribution post-approval, including by requiring REMS, with or without ETASU that balance risk mitigation, patient access, and burden on the health care delivery system. Under this comprehensive authority, FDA has continuously evaluated and re-evaluated the scientific evidence regarding mifepristone and the way in which it can be prescribed, distributed, and dispensed.

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Respectfully submitted,

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APPENDIX: LIST OF FOOD AND DRUG AND HEALTH LAW SCHOLARS

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Greer Donley, JD: Greer Donley is the John E. Murray Faculty Scholar and Associate Professor of Law at the University of Pittsburgh Law School. Her research focuses on reproductive rights, FDA law, and health law.

Lewis A. Grossman, JD, PhD: Lewis Grossman is a Professor of Law at the American University Washington College of Law. He teaches and writes in the areas of food and drug law, health law, American legal history, and civil procedure. He is the co-author of *Food and Drug Law: Cases and Materials* (5th Edition 2022) and has served as a member or legal consultant on four committees of the Health and Medicine Division (formerly the Institute of Medicine) of the National Academies of Sciences, Engineering, and Medicine.

Rachel Rebouché, JD, LLM: Rachel Rebouché is the Dean of the Temple University Beasley School of Law and the James E. Beasley Professor of Law. Professor Rebouché is a leading scholar in reproductive health law and family law. She has served as a co-investigator on two grant-funded research projects related to reproductive health, one housed at the Emory University Rollins School of Public Health and another funded by the World Health Organization.

Patricia J. Zettler, JD: Patricia J. Zettler is an Associate Professor of Law at the Ohio State University Moritz College of Law and a member of Ohio State's Drug Enforcement and Policy Center and its Comprehensive Cancer Center. Her research focuses on FDA law and policy, and she is a co-author of *Food and Drug Law: Cases and Materials* (5th Edition 2022). Before her academic career, she served as an associate chief counsel in FDA's Office of the Chief Counsel.

I. Glenn Cohen, JD: I. Glenn Cohen is a professor at Harvard Law School. His research focuses on bioethics and health law, with current projects in FDA law, abortion, and reproductive technologies.

Peter Barton Hutt, LLM, LLB: Peter Barton Hutt is a Senior Counsel at Covington & Burling LLP specializing in Food and Drug Law and a former Chief Counsel of FDA. He is the lead co-author of *Food and Drug Law: Cases and Materials* (5th Edition 2022) and has taught a full course on the subject at Harvard Law School for thirty consecutive years.

Allison M. Whelan, JD, MA: Allison M. Whelan is an Assistant Professor of Law at Georgia State University College of Law where her scholarship and teaching focuses on FDA law, reproductive justice, administrative law, and bioethics. Prior to her academic career, she practiced food and drug law at a large law firm.